K120243

JUN 27 2012

Section 6 – 510(k) Summary

1. Submitter Information:

GC AMERICA INC.
3737 W. 127th Street
Alsip, IL 60803

Contact Person: Mark Heiss, D.D.S.
Phone: (708) 926-3090
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Date Prepared: January 23, 2012

2. Device Name:

Proprietary Name: GAM-200
Classification Name: Dental Cement
Device Classification: Class II, 872.3275
Product Code: EMA

3. Predicate Devices:

| Company | Device | 510(k) No. | Date Cleared |
|---|---|---|---|
| GC America Inc. | G-CEM Automix (GAM-100) | K073283 | 02/20/2008 |
| KERR CORPORATION | Maxcem Elite (Maxcem 2) | K073209 | 01/29/2008 |

4. Description of Device:

GAM-200 is a dual-cured self-adhesive resin cement. The mixed cement is hardened through the polymerization activated by redox or photo initiator system. The adhesiveness to tooth structure develops with phosphoric ester monomers which form ionic bonds with calcium ions. The acidic monomers also can polymerize with frame-forming monomers.

The components consists of Paste A and B, which are filled in a one-body syringe. Both pastes are automixed with a mixing tip and directly applied to restorations or the prepared cavity.

5. Indications for Use:

1. Cementation of all types of all ceramic, resin and metal-based inlays, onlays, crowns and bridges.
2. Cementation of metal, ceramic, fiber posts, and cast post and cores.

6. Technological characteristics:

The curing mechanism of the predicates is polymerization of uncured methacrylate ester monomers. This reaction is caused by redox or photo initiator system. These devices contain an acidic ester monomer which develops adhesiveness to tooth structures. The applicant device also has a same curing and adhesive mechanism.

The setting time of GAM-200 comes in the same range of the comparative devices and the depth of cure is equivalent. These indicate the proper setting property of the applicant for clinical use. The applicant device also shows equivalent values in flexural strength, water sorption and solubility, which indicate the stability of materials in oral environment.

7. Substantial equivalence:
The applicant device complies with all the requirements of ISO 4049: 2009 (Dentistry - Polymer-based restorative materials). The bond strengths of the applicant in accordance with ISO 11405: 2003 are equivalent to the predicate devices. In terms of the biological evaluation, the cytotoxicity test in accordance with MTT Assay method showed that the applicant device is equivalent to the predicates.

8. Conclusion:
Thus, the new and predicate devices are the same in function, and similar in composition and intended use. This supports that the applicant device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 27 2012

Mr. Mark Heiss
Director, Regulatory Affairs
GC America, Incorporated
3737 West 127th Street
Alsip, Illinois 60803

Re: K120243
Trade/Device Name: GAM-200
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: May 9, 2012
Received: May 10, 2012

Dear Mr. Heiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120243

Section 5

Indications for Use

510(k) Number (if known): _____

Device Name: GAM-200

Indications for Use:

1. Cementation of all types of all ceramic, resin and metal-based inlays, onlays, crowns and bridges.
2. Cementation of metal, ceramic, fiber posts, and cast post and cores.

| | | |
|---|---|---|
| Prescription Use ___X___<br>(Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____<br>(21 CFR 801 Subpart C) |

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120243